

SOAH DOCKET NO. 453-02-3067.M2
[TWCC Docket No. M2-02-0455-01]

— <i>Petitioner</i>	§	BEFORE THE STATE OFFICE
	§	
	§	
VS.	§	OF
	§	
TEXAS WORKERS' COMPENSATION	§	ADMINISTRATIVE HEARINGS
COMMISSION, and AMERICAN	§	
INTERSTATE INSURANCE CO.,	§	
<i>Respondent.</i>	§	

DECISION AND ORDER

____ (Claimant) has appealed a decision of the Independent Review Organization (IRO). The IRO agreed with the determination made by American Interstate Insurance Co. (Carrier) which denied preauthorization for an IDET¹ procedure on Claimant. In this decision, the Administrative Law Judge (ALJ) finds that Claimant has not met its burden of showing it is entitled to preauthorization of the requested IDET procedure. Therefore, the ALJ agrees with the IRO decision, which denied preauthorization.

The hearing was convened on August 19, 2002, before Steven M. Rivas, Administrative Law Judge (ALJ). Claimant appeared and was assisted by Anthony Walker, Ombudsman. Carrier appeared and was represented by Beverly L. Vaughn, attorney. The record closed the same day.

I.
DISCUSSION

1. Background Facts

Claimant worked as a truck driver for Coastal Transportation before suffering a compensable injury on_____, while loading equipment onto a truck.² Some time following the injury, Claimant came under the care of Susan K. Linder, M.D.³ Under Dr. Linder's care, Claimant

¹ **Intradiscal Electrothermal Therapy** or Intradiscal Electrothermal Anuloplasty and Nucleotomy.

² Claimant has been out of work since the injury.

³ Claimant's first treating doctor was a Dr. Pentecost who referred Claimant to Dr. Linder. Dr. Pentecost's records or findings were not made part of the record.

underwent physical therapy before being referred to Phillip M. Cantu, M.D., who recommended Claimant undergo an IDET procedure to relieve back pain. After Dr. Cantu's request for preauthorization of IDET were denied by the Carrier, Claimant sought preauthorization through the IRO process.

2. Applicable Law

The Texas Labor Code contains the Texas Workers' Compensation Act (the Act) and provides the relevant statutory requirements regarding compensable treatment for workers' compensation claims. In particular, TEX. LAB. CODE ANN. § 408.021 provides in pertinent part:

(a) An employee who sustains a compensable injury is entitled to all health care reasonably required by the nature of the injury as and when needed. The employee is specifically entitled to health care that:

- (1) cures or relieves the effects naturally resulting from the compensable injury;
- (2) promotes recovery; or
- (3) enhances the ability of the employee to return to or retain employment.

* * *

Under TEX. LAB. CODE ANN. §401.011(19) health care includes all reasonable and necessary medical aid, medical examinations, medical treatment, medical diagnoses, medical evaluations, and medical services.

3. IRO Decision

The IRO issued its report on April 8, 2002, agreeing with Carrier's determination denying preauthorization. The Medical Case Review included with the IRO decision stated:

[T]here is clear indication of moderate central disk herniation with moderate central canal stenosis. If one reviews the criteria for IDET procedure, potential exclusion criteria clearly state that moderate to severe spinal or canal stenosis would exclude the patient from the procedure.

IDET procedure is clearly a revolutionary procedure and is fast becoming a part of the armamentarium of interventional pain management, but its success depends on careful selection of potential candidates for it.

1. Burden of Proof

Carrier contended under 28 TEX. ADMIN. CODE § 133.308(v), an IRO decision carries presumptive weight. Moreover, since Claimant lost before the IRO, he has the burden of proof, and in order to prevail Claimant must show that the IRO decision was contrary to the great weight of the evidence. Carrier further asserted that § 133.308(v) establishes a heightened standard of proof where IRO decisions are being appealed. Cases appealed from the IRO are fairly new to SOAH. This is the first time this ALJ has had to apply § 133.308(v). After considering the presumptive weight burden, the ALJ finds that Claimant did not meet his burden of proof.

E. Analysis

5. The IDET Procedure.

To adequately understand the IDET procedure, a brief overview of the spine is necessary. A person's spine is comprised of 23 bony segments referred to as vertebrae or discs. The discs make up the three regions of the spine: cervical, thoracic and lumbar. Under the lumbar region lies the sacrum, a triangular shaped bone. Each disc has a nucleus which is surrounded by connective tissue called anulus. The nucleus of a disc acts as a shock absorber to the spinal column. The nucleus is surrounded by layers of connective tissue called the anulus.

Following some kind of trauma to the patient, tears in the anulus sometimes appear. Pain is felt by the patient when the nerves of the spinal column penetrate through the anulus into the nucleus of the disc. The IDET procedure calls for a needle injected into the nucleus of a patient's disc, while under local anesthesia, to treat the torn anulus by heating a catheter (injected into the nucleus after the first needle) and killing the nerves that are penetrating the anulus. The procedure also reforms the connective tissue of the anulus. Dr. Cantu recommends a three-level IDET procedure to treat the discs in the following areas: L3-L4, L4-L5, L5-S1.

IDET is a rather new treatment of lower back pain but has shown to be effective in studies of patients who complained of lower back pain for at least six months prior to undergoing the procedure.⁴ In the study noted, of the 25 patients who underwent the IDET procedure, most achieved clinically meaningful and statistically significant improvement in pain and function level.⁵

6. IDET is an experimental procedure.

Claimant's main argument for requesting the IDET procedure is that it will relieve his lower back pain. Under TEX. LAB. CODE ANN. § 408.021(a)(1), a Claimant who suffers a compensable injury is entitled to health care that relieves the effects naturally resulting from the compensable injury. Dr. Cantu testified Claimant is a good candidate for the IDET procedure and should be entitled to receive preauthorization for IDET because the Saal study shows it will relieve his back pain.

⁴ Saal, Joel S. and Saal, Jeffrey A., *Management of Chronic Discogenic Low Back Pain With a Thermal Intradiscal Catheter: A Preliminary Report*, 25 Spine 382-388 (2000).

⁵ See *Id.*

Carrier asserts Claimant should not receive preauthorization because IDET is an experimental procedure that does not ensure Claimant's pain will be relieved. While IDET has not been around for many years, it may not deserve the label of experimental. The Saal study reported a positive success rate for patients who underwent the IDET procedure. Furthermore, according to Dr. Cantu's testimony, he has had excellent results using the IDET procedure on his patients. In 2001, Dr. Cantu performed the IDET procedure on 22 patients with a 90% success rate. Of the 23 IDET procedures performed in 2002, Dr. Cantu has a 100% success rate. Considering Dr. Cantu's experience and success rate with the IDET procedure, his testimony is compelling that Claimant is a good candidate for IDET.

7. Alternatives to IDET.

The alternatives to the IDET procedures are not preferred or recommended by Dr. Cantu. One such alternative is spinal fusion surgery, **a procedure that involves fusing together two or more vertebrae in the spine using either bone grafts or metal rods.** Spinal fusion is a major surgery and would require six months total recovery time including hospital care. IDET is an outpatient procedure costing a fraction of open surgery and patients typically recover after three months - half the recovery time of spinal surgery. Furthermore, if the IDET procedure is unsuccessful, Claimant can explore other options such as surgery. Whereas if surgery is unsuccessful, Claimant can not then undergo the IDET procedure.

Oral narcotic therapy is another option. It would require Claimant to take various medication to relieve his back pain caused by the anulus tears. According to Dr. Cantu, based on the high incidence of addiction, this treatment is not recommended for Claimant. While narcotic therapy may relieve Claimant's pain, the IDET procedure would relieve and cure Claimant's condition by repairing the torn anulus tissue covering the nucleus of the damaged discs.

8. IDET inclusion and exclusionary criteria.

a. *Saal study criteria*

The criteria for including and excluding potential claimants for the IDET procedure was first established by the Saal study of 25 patients. Patients were eligible for the IDET procedure if they met the following criteria: (1) six months of low back pain; (2) no improvement after comprehensive nonoperative care; (3) normal neurological findings; (4) negative results on straight leg raise; (5) MRI scans not showing neural compressive lesion; and (6) concordant pain reproduction with provocative discography at low pressurization.

Patients excluded from the study were those having: (1) inflammatory arthritis; (2) non-spinal conditions that could mimic lumbar pain; or (3) conditions that would preclude follow-up evaluations.

b. *Carrier's position*

Claimant does not fit into any of the exclusion criteria but Carrier asserts Claimant should not receive preauthorization for the IDET procedure because he does not fit one of the inclusion

criteria. Specifically, Carrier argued Claimant does not have an MRI scan not showing neural compressive lesion or spinal stenosis. A CT scan on September 26, 2001, revealed mild to moderate stenosis, or a narrowing of discs in the spinal column, at L4-L5 and L5-S1, two of the areas where Claimant seeks IDET treatment. Having considered the results of the CT scan of September 26, 2001, Dr. Cantu still recommends the IDET procedure for Claimant.

Dr. Cantu asserted Claimant should not be denied preauthorization of the IDET procedure because he did not fit into any of the exclusion criteria outlined in the Saal study. Dr. Cantu admitted Claimant did not meet one of the inclusion criteria but this factor alone should not be deemed a basis for exclusion.

Dr. Cantu's logic is flawed. In order to fit the inclusion criteria, a claimant must have an MRI record showing no stenosis. If an MRI indicates stenosis, that claimant does not fit one of the inclusion criteria and is therefore excluded.

3. *Spinal stenosis*

Dr. Cantu testified Claimant had no clinical evidence of stenosis that would preclude approval for the IDET procedure. Even though the MRI film showed moderate stenosis, it should not be considered actual stenosis unless the AP diameter is less than 12 millimeters. Dr. Cantu asserted Claimant's AP diameter is normal and is not less than 12 millimeters. Dr. Cantu did not cite a source for this position, nor did he adequately describe how the AP diameter relates to stenosis. Lumbar spinal stenosis is a condition involving any type of narrowing of the spinal canal or nerve-root canals.⁶ No distinction or alternate definition of stenosis was made at the hearing, or addressed in any of the documents leading up to the hearing. Therefore, no other definition of stenosis will be considered.

Dr. Cantu also testified the MRI done on Claimant was performed near the time of the injury and any disc showing stenosis at that time has definitely resorbed by now because Claimant has no physical symptoms of stenosis. Dr. Cantu asserted if the MRI was done now, there would be no showing of stenosis. However, Dr. Cantu admittedly pointed out he could not offer any proof that

⁶ [Http://www.spinalstenosis.org](http://www.spinalstenosis.org) footnote No. 1 Arnoldi, C. C. ; Brodsky, A. E.; Cauchoux, J. ; Crock, H.V. ; Dommissie, G. F.; Edgar, M. A. ; Gargano, F. P.; Jacobson, R. E.; Kirkaldy-Willis, W. H.; Kurihara, A.; Langenskiold, A; Macnab, I; McIvor, G. W. D.; Newman, P. H.; Paine, K. W. W.; Russin, L. A.; Sheldon, J.; Tile, M.; Urist, M.R.; Wilson, W.E. and Wiltse, L.L.: 'Lumbar Spinal Stenosis and Nerve Root Entrapment Syndromes. Definition and Classification.' 1976 Clin Orthop., 115: 4-5.

this would be the case.

d. *Criteria as a cautionary guideline*

The criteria in the Saal study was developed to determine patient eligibility for the 25 patients who participated in the study. When the study was published, it included the criteria, the procedure and the results under one heading and was referred to as a preliminary report. The basis of the study was show the how patients with low back pain responded to the IDET procedure.

According to Dr. Cantu, the criteria developed by the Saal study should not be recognized as strict regulations but should rather be consulted and used as a cautionary guideline for practicing physicians who recommend the IDET procedure be performed on patients.

Dr. Cantu wants the ALJ to consider the Saal study as it pertains to the IDET procedure and the positive results of the patients who underwent the procedure. However, in regard to the criteria established by Drs. Saal and Saal, Dr. Cantu wants the ALJ to refer to it as a cautionary guideline even though the study itself does not refer to the criteria as such. Dr. Cantu cannot have it both ways. If the Saal study is to be considered in preauthorizing the IDET procedure, then the ALJ will consider the study as it is published. Since the study does not refer to the criteria as cautionary guidelines, the ALJ will not either.

The criteria was established for a reason. If the presence of stenosis was meant as a cautionary guideline rather than strict criteria as Dr. Cantu asserted, the Saal study would have said so. Because Claimant has spinal stenosis present, he fits the exclusion criteria established by the Saal study and should be denied preauthorization at this time.

4. *Conclusion.*

Claimant has been out of work since the injury and indicated he would very much like to return to work but for his unrelenting back pain. A cost-effective, outpatient procedure with a reasonable recovery time is, understandably, a favorable option in the eyes of the Claimant. The ALJ found Claimant's testimony compelling and commends the Ombudsman's presentation of the evidence.

It is the evidence, however, that the ALJ must consider in deciding this matter. The leading, and perhaps only, study of the IDET procedure was developed by Drs. Saal and Saal, pioneers in their field. The IDET procedure was designed to be followed strictly in order to achieve the desired results of back pain relief. The criteria established in the Saal study is in place to ensure only those patients who are ripe for the procedure undergo the procedure. As the procedure itself was meant to be followed so was the criteria.

Claimant does not meet one of the inclusion criteria; therefore, he must possess a condition that excludes him from having the IDET procedure based on the Saal study. Since there is no other study to draw further qualifications, the Saal study is given great weight. Because Claimant is excluded from participating in the IDET procedure, he cannot receive preauthorization for the procedure.

For the foregoing reasons, the ALJ concludes that the requested IDET procedure is not reasonable or medically necessary for Claimant's compensable injury, and should not be

preauthorized.

II. FINDINGS OF FACTS

1. __(Claimant), was a truck driver with Coastal Transportation.
2. On_____, Claimant sustained a compensable work-related injury while loading equipment onto a truck.
3. At the time of Claimant's compensable injury, Claimant's employer was covered by American Interstate Insurance Company (Carrier) under the Texas Workers' Compensation Act.
4. Claimant came under the care of Susan K. Linder, M.D., who referred Claimant to Phillip M. Cantu, M.D., for treatment of lower back pain.
5. Dr. Cantu found Claimant had damaged discs in his spinal column at L3-L4, L4-L5, and L5-S1.
6. Dr. Cantu recommended Claimant undergo an IDET procedure to cure the damaged the discs.
7. Carrier denied Dr. Cantu's request for the IDET procedure.
8. Claimant requested medical dispute resolution through an Independent Review Organization (IRO).
9. The IRO reviewed the dispute and issued a decision on April 8, 2002, finding that the requested IDET procedure was not medically necessary.
10. Claimant appealed the IRO decision to the State Office of Administrative Hearings (SOAH).
11. Notice of the hearing in this case was mailed to the parties on June 26, 2002. The notice contained a statement of the time, place, and nature of the hearing; a statement of the legal authority and jurisdiction under which the hearing was to be held; a reference to the particular sections of the statutes and rules involved; and a short, plain statement of the matters asserted. In the notice, the Commission's staff indicated that it would not participate in the hearing.
12. The hearing was held on August 19, 2002, with Administrative Law Judge (ALJ) Steven M. Rivas presiding. Claimant appeared with Anthony Walker, Ombudsman. Carrier appeared through Beverly L. Vaughn, attorney. The hearing was adjourned and the record closed the same day.
13. Claimant presented a study by Drs. Saal and Saal that indicated Claimant might be relieved of his back pain if he underwent the requested IDET procedure.
14. Claimant presented evidence of the inclusion and exclusion criteria noted in the Saal study of

25 patients who underwent the IDET procedure.

15. One of the inclusion criteria is that a patient have MRI scans not showing neural compressive lesion or stenosis.
16. Based on an MRI finding in 2001, Claimant has stenosis of the lumbar spine.
17. A patient who has stenosis does not meet one of the inclusion criteria outlined in the Saal study.
18. If Claimant does not meet one of the inclusion criteria he is considered excluded from approval to undergo the IDET procedure based on the Saal study.
19. The criteria set out in the Saal study are not referred to as cautionary guidelines when recommending the IDET procedure.
20. Dr. Cantu considered Claimant's past history of stenosis when recommending the IDET procedure and in doing so, Dr. Cantu did not use the criteria correctly.
21. The IRO found Claimant should not receive preauthorization because of the presence of spinal stenosis.
22. Claimant did not present evidence that the IRO decision is not supported by the preponderance of the evidence and goes against the great weight of the medical evidence.

III. CONCLUSIONS OF LAW

- 1 The Commission has jurisdiction over this matter pursuant to TEX. LAB. CODE § 413.031.
2. SOAH has jurisdiction over this proceeding, including the authority to issue a decision and order, pursuant to TEX. LAB. CODE ANN. § 413.031(d) and TEX. GOV'T CODE ANN. ch. 2003.
3. Travis County timely filed its notice of appeal, as specified in 28 TEX. ADMIN. CODE § 148.3.
4. Proper and timely notice of the hearing was effected upon the parties according to TEX. GOV'T CODE § 2001.052 and 28 TEX. ADMIN. CODE § 148.4.
5. Under TEX. LABOR CODE § 408.021(a)(1), an employee who sustains a compensable injury is entitled to all health care reasonably required by the nature of the injury as and when needed that cures or relieves the effects naturally resulting from the compensable injury.
6. Under 28 TEX. ADMIN. CODE § 133.308(v), **in all appeals from reviews of prospective or retrospective necessity disputes, the IRO decision has presumptive weight.**
7. Claimant did not meet his burden of proof to show that the IDET procedure should be

preauthorized.

8. Based on the above Findings of Facts and Conclusions of Law, Claimant's request for preauthorization of the IDET procedure should be denied.

ORDER

IT IS ORDERED THAT the IDET procedure requested by Claimant not be preauthorized.

Signed this 16th day of September, 2002.

STEVEN M. RIVAS
STATE OFFICE OF ADMINISTRATIVE HEARINGS
ADMINISTRATIVE LAW JUDGE